

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

MALVERN PANALYTICAL INC.,

Plaintiff,

v.

TA INSTRUMENTS-WATERS LLC and
WATERS TECHNOLOGIES CORPORATION,

Defendants.

C.A. No. 1:19-cv-02157-RGA

JURY TRIAL DEMANDED

**DEFENDANTS' ANSWER AND AFFIRMATIVE DEFENSES
TO FIRST AMENDED COMPLAINT**

Defendants TA Instruments-Waters LLC and Waters Technologies Corporation (collectively, "Defendants"), by and through their undersigned counsel, hereby submit this Answer and Affirmative Defenses to the First Amended Complaint of Plaintiff Malvern Panalytical Inc. ("Malvern"). (D.I. 14.) Pursuant to Federal Rule of Civil Procedure 8(b)(3), Defendants deny each and every allegation in Malvern's First Amended Complaint except those expressly admitted below.

NATURE OF THE ACTION

1. This paragraph contains statements to which no response is required. To the extent any response is required, Defendants admit that Malvern purports to bring an action for patent infringement. Defendants deny any remaining allegations in this paragraph.

PARTIES

2. Defendants lack sufficient knowledge or information to admit or deny, and on that basis deny the allegations.

3. Defendants admit that Malvern supplies scientific instruments used for analysis of materials. Defendants also admit that isothermal titration calorimeters (ITCs) measure the heat

either released or absorbed during chemical reactions, including biomolecular binding events. Defendants lack sufficient information or knowledge to admit or deny the remaining allegations in this paragraph, and on that basis deny the allegations.

4. Defendants admit that TA Instruments-Waters LLC is a corporation organized and existing under the laws of the State of Delaware, with corporate headquarters and a principal place of business in New Castle, DE, and that TA Instruments manufactures ITC devices. Defendants deny that “Waters Technology Corporation” is the parent company of TA Instruments but admit that “Waters Technologies Corporation” is the parent company of TA Instruments. Further, Defendants admit that Waters Technologies Corporation is a corporation organized and existing under the laws of the State of Delaware, and has a principal place of business in Milford, MA. Defendants deny the remaining allegations in this paragraph.

JURISDICTION AND VENUE

5. This paragraph contains statements to which no response is required. To the extent any response is required, Defendants admit that Malvern purports to bring this action under the patent laws of the United States, pursuant to Title 35 of the United States Code. Further, the Court dismissed Malvern’s claims of contributory infringement as to all asserted patents. (*See* D.I. 25 at 2.) Accordingly, Defendants deny any allegation directed to those claims.

6. Defendants admit that this Court has subject matter jurisdiction over any patent claim in Malvern’s First Amended Complaint under 28 U.S.C. §§ 1331 and 1338(a) that was not dismissed in the Court’s May 5, 2020 order.

7. Defendants admit that this Court has personal jurisdiction over Defendants for the purposes of this litigation.

8. Defendants admit that venue is proper in this District for purposes of this litigation.

TECHNICAL BACKGROUND

9. Defendants admit that chemical processes, such as the interactions of two compounds, absorb or release energy that may be measured in units of calories. Defendants further admit that measuring energy absorbed or released when two compounds interact can reveal important properties about the interaction, such as: (1) binding affinity (the strength of the binding interaction between the two compounds); (2) stoichiometry (the ratio at which any two compounds interact); and (3) binding enthalpy (the amount of energy absorbed or released when two compounds interact). Defendants further admit that these properties may give insight into how a given chemical process works, and may be important in the development of new chemical products, testing existing products, or simply understanding natural phenomena. Defendants lack sufficient knowledge or information to admit or deny the remaining allegations of this paragraph, and on that basis deny them.

10. Defendants admit that microcalorimetry is a technique for measuring the heat absorbed or released when two compounds interact and that microcalorimeters can detect extremely small amounts of energy, as heat, often measured in microcalories, or μcal s.

11. Defendants admit that microcalorimetry has applications in research and development across several disciplines. Defendants further admit that, in chemistry, researchers can use microcalorimetry to determine thermal properties of a substance and that biotechnology researchers can use microcalorimetry to determine the binding strength between a drug and a protein to assess the viability of that drug in treating a medical condition. Defendants further admit that materials engineering researchers can use microcalorimetry to determine the melting

point of a new material composition. Defendants lack sufficient knowledge or information to admit or deny the remaining allegations of this paragraph, and on that basis deny them.

12. Defendants admit that a microcalorimeter works by measuring the amount of energy a substance or mixture consumes or releases at a given temperature and that one microcalorimeter configuration is the ITC.

13. Defendants admit that in a typical ITC setup, there are two chambers: a sample cell and a reference cell. Defendants further admit that the sample cell may contain a sample (for example, a protein) suspended in a buffer solution and the reference cell may contain water or a buffer solution. Defendants further admit that a syringe and needle are typically used to titrate (*i.e.*, deliver drop-by-drop) a ligand (such as a molecule that binds with the sample, for example, a drug) into the sample cell. Defendants further admit that during the experiment, the temperature in the two cells is held constant (hence the reference to “isothermal” in ITC).

14. Defendants admit that a user begins an ITC experiment by controlling the syringe to introduce a measured amount of ligand (also called the titrant) into the sample cell. Defendants further admit that in some ITCs, a stirring assembly mixes the ligand and the sample and the resulting reaction either produces heat (exothermic) or consumes heat (endothermic). Defendants further admit that the ITC measures the amount of energy it takes to keep the sample cell at the same temperature as the reference cell to which no ligand is added.

15. Defendants admit that the compounds tested using microcalorimetry, known as “samples,” may be expensive and produced in small amounts. Defendants further admit that a single experiment may require multiple trials, with each trial requiring a fresh sample and that a failed or faulty experiment may require an entirely new sample. Defendants further admit that it is desirable for microcalorimeters to be designed to reduce the amount of sample needed for each

experiment. Defendants lack sufficient knowledge or information to admit or deny the remaining allegations of this paragraph, and on that basis deny them.

COMPANY BACKGROUND

16. Defendants lack sufficient knowledge or information to admit or deny allegations in this paragraph, and on that basis deny those allegations.

17. Defendants lack sufficient knowledge or information to admit or deny allegations in this paragraph, and on that basis deny those allegations.

18. Defendants admit that MicroCal supplied microcalorimetry instrumentation. Defendants lack sufficient knowledge or information to admit or deny the remaining allegations in this paragraph, and on that basis deny those allegations.

19. Defendants admit that MicroCal introduced the Omega ITC around 1989. Defendants lack sufficient knowledge or information to admit or deny the remaining allegations in this paragraph, and on that basis deny those allegations.

20. Defendants admit that MicroCal developed the ITC200 around 2007, developed the Auto ITC 200, and hired Dr. Plotnikov in the 1990s. Defendants lack sufficient knowledge or information to admit or deny the remaining allegations in this paragraph, and on that basis deny those allegations.

21. Admitted.

MALVERN'S PATENTED INVENTIONS

Plotnikov Patents

22. Defendants admit that Exhibit A to the First Amended Complaint purports to be U.S. Patent No. 8,449,175, that Exhibit A is titled "Isothermal Titration Microcalorimeter Apparatus and Method of Use," that Exhibit A purports to claim priority to an earlier application filed November 1, 2007, that Exhibit A was purportedly submitted for supplemental examination

in 2016, and that Exhibit A purportedly received a certificate of reexamination issued on February 21, 2018. Defendants lack sufficient knowledge or information to admit or deny the remaining allegations of this paragraph, and on that basis deny those allegations.

23. Defendants admit that Exhibit B to the First Amended Complaint purports to be U.S. Patent No. 8,827,549, that Exhibit B is titled “Isothermal Titration Microcalorimeter Apparatus and Method of Use,” that Exhibit B purports to claim priority to an earlier application filed November 1, 2007, that Exhibit B was purportedly submitted for supplemental examination in 2016, and that Exhibit B purportedly received a certificate of reexamination on February 23, 2018. Defendants lack sufficient knowledge or information to admit or deny the remaining allegations of this paragraph, and on that basis deny those allegations.

24. Defendants admit that the purported inventors listed on the ’175 Patent and ’549 Patent are Valerian Plotnikov and Andrzej Rochalski. Defendants deny that the ’175 Patent and the ’549 Patent are valid and enforceable and deny any remaining allegations in this paragraph.

25. Denied.

26. Denied.

27. Denied.

28. Denied.

Broga Patents

29. Defendants admit that Exhibit C to the First Amended Complaint purports to be U.S. Patent No. 9,404,876, that Exhibit C is titled “Automatic Isothermal Titration Microcalorimeter Apparatus and Method of Use,” that Exhibit C purports to claim priority to an earlier application filed December 2, 2008, and that Exhibit C purports to have been issued on

August 2, 2016. Defendants lack sufficient knowledge or information to admit or deny the remaining allegations of this paragraph, and on that basis deny those allegations.

30. Defendants admit that Exhibit D to the First Amended Complaint purports to be U.S. Patent No. 10,036,715, that Exhibit D is titled “Automatic Isothermal Titration Microcalorimeter Apparatus and Method of Use,” that Exhibit D purports to be a continuation of the ’876 Patent, that Exhibit D purports to claim priority to an earlier application filed December 2, 2008, and that Exhibit D purports to have been issued on July 31, 2018. Defendants lack sufficient knowledge or information to admit or deny the remaining allegations of this paragraph, and on that basis deny those allegations.

31. Defendants admit that Exhibit E to the First Amended Complaint purports to be U.S. Patent No. 10,254,239, that Exhibit E is titled “Automatic Isothermal Titration Microcalorimeter Apparatus and Method of Use,” that Exhibit E purports to be a continuation of the ’715 Patent, that Exhibit E purports to claim priority to an earlier application filed December 2, 2008, and that Exhibit E purports to have been issued on April 9, 2019. Defendants lack sufficient knowledge or information to admit or deny the remaining allegations of this paragraph, and on that basis deny those allegations.

32. Defendants admit that the purported inventors listed on the ’876 Patent, the ’175 Patent, and the ’239 Patent are Martin Broga, Phillip Price, and Stephen Smith. Defendants deny that the ’876 Patent, the ’175 Patent, and the ’239 Patent are valid and enforceable and deny any remaining allegations in this paragraph.

33. Denied.

Patent Markings

34. Defendants lack sufficient knowledge or information to admit or deny the remaining allegations of this paragraph, and on that basis deny those allegations.

35. Defendants lack sufficient knowledge or information to admit or deny the remaining allegations of this paragraph, and on that basis deny those allegations.

THE [ALLEGED] ACCUSED PRODUCTS

36. Defendants admit that the TA Affinity ITC is a semi-automatic ITC and the TA Affinity ITC Auto is a fully-automated ITC.

37. Denied.

38. Defendants admit that claim 9 of the '175 Patent includes the cited elements.

39. Defendants admit that claim 1 of the '549 Patent includes the cited elements.

40. Denied.

41. Denied.

42. Denied.

43. Denied.

44. Denied.

45. Denied.

46. Denied.

47. Denied.

48. Denied.

49. Defendants admit that claim 1 of the '876 Patent includes the cited elements.

50. Defendants admit that claim 1 of the '715 Patent includes the cited elements.

51. Defendants admit that claim 1 of the '239 Patent includes the cited elements.

52. Denied.

53. Denied.

54. Denied.

55. Denied.

56. Denied.

57. Denied.

58. Denied.

59. Denied.

DEFENDANTS' [ALLEGED] KNOWLEDGE OF THE ASSERTED PATENTS

60. Defendants admit that it competes with Malvern in the market for ITCs.

Defendants deny the remaining allegations in this paragraph.

61. Denied.

62. Defendants admit that Malvern sent a letter to TA Instruments on September 2, 2015 purporting to assert infringement of the '175 Patent and the '549 Patent, prior to supplemental examination, and included claim charts. Defendants deny that Malvern asserted infringement of the Affinity ITC.

63. Because Malvern does not explain what it means to “monitor,” Defendants lack sufficient knowledge or information to determine the truth or falsity of the allegation and therefore deny it.

64. Denied.

COUNT I: [ALLEGED] INFRINGEMENT OF U.S. PATENT NO. 8,449,175

65. Defendants repeat and reassert all responses to the preceding paragraphs as if fully set forth herein.

66. Denied.

67. Denied.

68. The Court dismissed Malvern’s claim of contributory infringement of the '175 Patent. (*See* D.I. 25 at 2.) Accordingly, Defendants deny any allegations directed to that claim.

69. The Court dismissed Malvern's claims of willful infringement of the '175 Patent. (See D.I. 25 at 1.) Accordingly, Defendants deny any allegations directed to that claim.

Defendants deny any remaining allegations in this paragraph.

70. Denied.

71. Denied.

72. Denied.

COUNT II: [ALLEGED] INFRINGEMENT OF U.S. PATENT NO. 8,827,549

73. Defendants repeat and reassert all responses to the preceding paragraphs as if fully set forth herein.

74. Denied.

75. Denied.

76. The Court dismissed Malvern's claim of contributory infringement of the '549 Patent. (See D.I. 25 at 2.) Accordingly, Defendants deny any allegations directed to that claim.

77. The Court dismissed Malvern's claims of willful infringement of the '549 Patent. (See D.I. 25 at 1.) Accordingly, Defendants deny any allegations directed to that claim.

Defendants deny any remaining allegations in this paragraph.

78. Denied.

79. Denied.

80. Denied.

COUNT III: [ALLEGED] INFRINGEMENT OF U.S. PATENT NO. 9,404,876

81. Defendants repeat and reassert all responses to the preceding paragraphs as if fully set forth herein.

82. Denied.

83. Denied.

84. The Court dismissed Malvern's claim of contributory infringement of the '876 Patent. Accordingly, Defendants deny any allegations directed to that claim.

85. The Court dismissed Malvern's claims of willful infringement of the '876 Patent. Accordingly, Defendants deny any allegations directed to that claim. (*See* D.I. 25 at 1-2.) Defendants deny any remaining allegations in this paragraph.

86. Denied.

87. Denied.

88. Denied.

COUNT IV: [ALLEGED] INFRINGEMENT OF U.S. PATENT NO. 10,036,715

89. Defendants repeat and reassert all responses to the preceding paragraphs as if fully set forth herein.

90. Denied.

91. Denied.

92. The Court dismissed Malvern's claim of contributory infringement of the '715 Patent. (*See* D.I. 25 at 2.) Accordingly, Defendants deny any allegations directed to that claim.

93. The Court dismissed Malvern's claims of willful infringement of the '715 Patent. (*See* D.I. 25 at 1-2.) Accordingly, Defendants deny any allegations directed to that claim. Defendants deny any remaining allegations in this paragraph.

94. Denied.

95. Denied.

96. Denied.

COUNT V: [ALLEGED] INFRINGEMENT OF U.S. PATENT NO. 10,254,239

97. Defendants repeat and reassert all responses to the preceding paragraphs as if fully set forth herein.

98. Denied.

99. Denied.

100. The Court dismissed Malvern's claim of contributory infringement of the '239 Patent. (*See* D.I. 25 at 2.) Accordingly, Defendants deny any allegations directed to that claim.

101. The Court dismissed Malvern's claims of willful infringement of the '239 Patent. Accordingly, Defendants deny any allegations directed to that claim. (*See* D.I. 25 at 1-2.) Defendants deny any remaining allegations in this paragraph.

102. Denied.

103. Denied.

104. Denied.

ANSWER TO MALVERN'S PRAYER FOR RELIEF

Defendants deny that Malvern is entitled to any of the relief requested.

JURY DEMAND

Defendants acknowledge that the First Amended Complaint sets forth a demand for a jury trial.

AFFIRMATIVE DEFENSES

Without any admission as to the burden of proof, Defendants assert the following defenses.

FIRST AFFIRMATIVE DEFENSE

1. Malvern's First Amended Complaint fails to state a claim upon which relief can be granted, for any of the Asserted Patents.

SECOND AFFIRMATIVE DEFENSE

2. Defendants have not infringed, and are not infringing, directly, indirectly, or by inducement, any valid claim of the Asserted Patents. Defendants are not liable in any respect for any alleged infringement of any claim of the Asserted Patents by any other individual or entity.

THIRD AFFIRMATIVE DEFENSE

3. Each claim of the Asserted Patents is invalid for failing to comply with one or more of the requirements of patentability under 35 U.S.C. §§ 101, 102, 103, and 112.

FOURTH AFFIRMATIVE DEFENSE

4. Malvern is barred from relief under the doctrine of prosecution history estoppel.

FIFTH AFFIRMATIVE DEFENSE

5. The claims of the Asserted Patents are barred by the judicially-created doctrine of obviousness-type double patenting.

SIXTH AFFIRMATIVE DEFENSE

6. Malvern's infringement claims and requests for relief are limited by 35 U.S.C. § 286 and/or § 287.

SEVENTH AFFIRMATIVE DEFENSE

7. Malvern is not entitled to an award of enhanced damages or its reasonable attorneys' fees.

RESERVATION OF ALL AFFIRMATIVE DEFENSES

8. Defendants reserve all affirmative defenses under Federal Rule of Civil Procedure 8(c), the Patent Laws of the United States, and any other defenses at law or in equity that may exist now or that may be available in the future based on discovery and further factual investigation in this action.

DEMAND FOR JURY TRIAL

Pursuant to Fed. R. Civ. P. 38(b), Defendants demand a trial by jury for all issues so triable.

PRAYER FOR RELIEF

WHEREFORE, Defendants respectfully request the following relief:

- A. The entry of judgment that Defendants have not directly infringed or induced infringement of any valid claim of any Asserted Patents;
- B. The entry of judgment finding that each of the Asserted Patents is invalid;
- C. The entry of judgment that Malvern is not entitled to any of the relief requested in its First Amended Complaint;
- D. The entry of judgment that this case constitutes an exceptional case under 35 U.S.C. § 285 and Defendants are entitled to an award of its attorneys' fees;
- E. Award Defendants its costs and disbursements of this action; and
- F. Award Defendants any other relief that the Court may deem just and proper.

DATED: May 19, 2020

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CERTIFICATE OF SERVICE

I, Karen L. Pascale, Esquire, hereby certify that on May 19, 2020, I caused to be electronically filed a true and correct copy of the foregoing document with the Clerk of the Court using CM/ECF (which will send notification that such filing is available for viewing and downloading to all registered counsel), and in addition caused true and correct copies of the foregoing document to be served upon the following counsel of record by e-mail:

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